REMARKS

Summary of the Amendment

No claims are herein amended. Claims 224-243 and 245-289 are pending and under consideration.

Summary of the Official Action

In the instant Office Action, the Examiner rejected claims 224-243 and 245-289 over the applied art of record. By the present remarks, Applicant submits that the rejection has been overcome, and respectfully request reconsideration of the outstanding Office Action and allowance of the present application.

Interview of December 8, 2010

Applicant appreciates the courtesy extended by Examiner Fortuna in the telephone Interview of December 8, 2010.

In the Interview, Applicant's representative discussed the obviousness rejection and in particular the following:

(1) that the claims recite that both the tissue web and transfer device or transfer belt pass through the winding nip utilizing the recited line force;

(2) that Figs. 1 and 2 of CLARKE and the description thereof indicate that CLARKE is not concerned with forming a winding nip. Reel spool 37 or 37' can be positioned in locations which do not form a nip;

(3) that while each of BEISSWANGER, MADRZAK and PFEIFFER appear to teach devices

for controlling a winding nip, none of these documents do so by passing a belt (or transfer device) and web through such a nip;

(4) that the claims recite a mechanism for at least one of controlling and measuring a line force in the winding nip in which the web and transfer device or belt pass; and

(5) that none of the applied documents specifically teach such a mechanism. While it true that KLERELID contains language on how a reel-up can utilize relatively low nip loads of 100-250 N/m (see col. 9, lines 43-53), there is no disclosed device or mechanism for controlling or measuring the noted values in KLERELID. Nor is apparent that the recited nip load necessarily requires such a device or mechanism.

Regarding Applicant's second point, the Examiner indicated that he was relying on the different embodiment of Fig. 4 in CLARKE, not that of Figs. 1 and 2, which was asserted to teach a winding nip designated by the reference letter "N".

Applicant's representative responded by noting that CLARKE did not appear to teach or suggest the so-called nip N was to be maintained or controlled in the recited manner in reference to reel 37a.

Regarding Applicant's first and third - fifth points, the Examiner did not disagree, but asserted that KLERELID can be interpreted to inherently utilize the recited mechanism for controlling and/or measuring a line force in the winding nip, and specifically noted that such devices were know in the art.

Applicant's representative responded to the Examiner by noting that no prior art has been identified by the Examiner in this case which discloses or suggests passing a tissue web and transfer device or belt through a winding nip utilizing the recited line force as well as a mechanism for

controlling and/or measuring a line force in the winding nip in combination with the other recited features.

In response, the Examiner reiterated that the asserted combination of teachings set forth in the obviousness rejection in the Final Office Action was reasonable and, at this point, would be maintained.

The Examiner, however, did indicate that upon receiving Applicant's response he would carefully evaluate the claims once again, and specifically the dependent claims, to determine whether allowable subject matter could be indicated in an effort to advance prosecution.

Traversal of Rejection Under 35 U.S.C. § 103

Applicant traverses the rejection of claims 224-243 and 245-289 under 35 U.S.C. § 103(a) as being unpatentable over US Patent Application Publication No. 2003/0111199 to CLARKE et al. in view of any one of the following documents; US 2001/0052560 to BEISSWANGER et al. or US 6,250,580 to MADRZAK et al. or US 3,599,889 to PFEIFFER or US 6,797,115 to KLERELID et al.

The Examiner asserts that CLARKE, and specifically Fig. 4, teaches or suggests each of the features recited in these claims with the exception of the line force controlling or measuring mechanism and the recited line force. However, he asserts that such devices are known from each of the secondary documents. Applicant respectfully disagrees.

Applicant respectfully submits that this rejection is improper because no proper combination of CLARKE and any one of BEISSWANGER, MADRZAK, PFEIFFER or KLERELID under 35 U.S.C. § 103(a) discloses or suggests: inter alia, at least one drying cylinder, a creping doctor arranged on the at least one drying cylinder, a winding device for winding up the tissue web, the

winding device comprising a winding nip formed between a winding drum and a spool, a transfer device at least largely bridging an entire distance between the creping doctor and the winding device and moves around the winding drum of the winding device, a free web draw arranged between the creping doctor and the winding device, and a mechanism for at least one of controlling and measuring a line force in the winding nip, wherein the tissue web is supported on only one side by the transfer device between the free web draw and the winding nip, and wherein the line force is less than or equal to 0.8 kN/m, as recited in amended independent claim 224; and inter alia, at least one drying cylinder, a creping doctor arranged on the at least one drying cylinder, a winding device for winding up the tissue web, the winding device comprising a winding nip formed between a winding drum and a spool, a transfer belt at least largely bridging an entire distance between the creping doctor and the winding device and moving around the winding drum of the winding device; a free web draw arranged between the creping doctor and the winding device, and a mechanism for at least one of controlling and measuring a line force in the winding nip, wherein the tissue web is supported on only one side by the transfer belt between the free web draw and the winding nip and the tissue web has an opposite unsupported side between the creping doctor and the winding device, and wherein the line force is less than or equal to 0.8 kN/m, as recited in amended independent claim 274.

Applicant does not dispute that CLARKE teaches a paper machine utilizing a free web draw between a doctor and a transfer belt (see, e.g., Fig. 4) or that Fig. 4 of CLARKE arguably shows a winding nip between reel drum 36a and spool 37a (see paragraph [0036]). However, it is submitted that CLARKE does not teach or suggest a mechanism for at least one of controlling and measuring a

line force in the winding nip, much less, that the line force is less than or equal to 0.8 kN/m. Indeed, the Examiner has acknowledged as much in the instant Office Action.

BEISSWANGER, MADRZAK and PFEIFFER do not cure the deficiencies of CLARKE. While it is true that each of BEISSWANGER, MADRZAK and PFEIFFER teaches devices for controlling a winding nip, none of these documents do so by passing a belt (or transfer device) and tissue web through such a nip. Indeed, the Examiner appeared to acknowledged as much in the Interview of December 8, 2010.

KLERELID also does not cure the deficiencies of CLARKE. As noted in the Interview of December 8, 2010, while it true that KLERELID contains language regarding how a reel-up can utilize relatively low nip loads of 100-250 N/m (see col. 9, lines 43-53), there is no disclosed device or mechanism in KLERELID for controlling or measuring the noted values. Nor is apparent that the recited nip load necessarily requires such a device or mechanism.

Nor does Applicant agree with the Examiner's assertion, emphasized in the Interview of December 8, 2010, that KLERELID can be interpreted to inherently utilize the recited mechanism for controlling and/or measuring a line force in the winding nip. Even assuming that such devices were known in the art (as alleged by the Examiner in the Interview of December 8, 2010), no prior art has been identified by the Examiner in this case which discloses or suggests passing a tissue web and transfer device or belt through a winding nip utilizing the recited line force as well as a mechanism for controlling and/or measuring a line force in the winding nip, much less, in combination with the other recited features.

Furthermore, the Examiner's inherency argument appears inconsistent with the non-precedential Board decision *Ex parte O'BRIEN* et al. which, in citing *Continental Can Co. v.*

Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991), explains on pages 5 and 6 that "when a reference is silent about an asserted inherent characteristic, it must be clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." It is respectfully submitted that the Examiner has not demonstrated "that the missing descriptive matter is necessarily present in the thing described in the reference", much less, "that it would be so recognized by persons of ordinary skill". At the very least, the Examiner should set forth prior art demonstrating that one cannot achieve the disclosed nip loads of KLERELID without using a mechanism for controlling and/or measuring a line force in the winding nip that corresponds to that recited in Applicant's claims. It is noted that this argument has not even been specifically alleged by the Examiner in the pending application. Moreover, if the Examiner is correct that one having ordinary skill in the art well knows to use such a mechanism in a winding nip receiving therein a tissue web and transfer device or belt, it should pose little difficulty in providing such evidence in the prior art. However, the record as it stands does not appear to support the Examiner's inherency assertion consistent with *Ex parte O'BRIEN*.

For the foregoing reasons and because these documents fails to disclose or suggest the above-noted features of the instant invention, Applicant submits that these documents fail to disclose or suggest each and every recited feature of claims 224 and 274. Accordingly, Applicant submits that the Examiner has failed to provide an adequate evidentiary basis to support a rejection of obviousness under 35 U.S.C. § 103(a), and that the instant rejection is improper.

Finally, Applicant submits that dependent claims 225-243, 245-273 and 275-289 are allowable at least for the reason that these claims depend from an allowable base claim and because these claims recite additional features that further define the present invention. In particular,

Applicant submits that CLARKE in combination with any one of BEISSWANGER, MADRZAK, PFEIFFER or KLERELID cannot be read to disclose or suggest each of the additional features recited in these claims. The Examiner's assertion that certain claim features not taught by the applied art are well known is, at the very least, insufficient to demonstrate obviousness because no evidence has been presented to support this assertion and features are recited in combination with other features and require an obviousness analysis consistent with current USPTO rules.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of this rejection and further requests that the above noted claims be indicated as allowable.

Application is Allowable

Thus, Applicant respectfully submits that each and every pending claim of the present invention meets the requirements for patentability under 35 U.S.C. §§ 112, 102 and 103, and respectfully request the Examiner to indicate allowance of each and every pending claim.

Authorization to Charge Deposit Account

The Commissioner is authorized to charge to Deposit Account No. 19-0089 any necessary fees, including any extensions of time fees required to place the application in condition for allowance by Examiner's Amendment, in order to maintain pendency of this application.

CONCLUSION

In view of the foregoing, it is submitted that none of the references of record, either taken alone or in any proper combination thereof, anticipate or render obvious the Applicant's invention, as recited in each of the pending claims. The applied references of record have been discussed and

distinguished, while significant claimed features of the present invention have been pointed out.

Accordingly, reconsideration of the outstanding Office Action and allowance of the present application and all the claims therein are respectfully requested and now believed to be appropriate.

Respectfully submitted,
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DENNIS O'BRIEN and CARL YEE

Appeal 2009-005178
Application 10/725,178
Technology Center 3700

Decided: October 15, 2009

Before LINDA E. HORNER, STEFAN STAICOVICI, and
KEN B. BARRETT, *Administrative Patent Judges.*

STAICOVICI, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

Dennis O'Brien et al. (Appellants) appeal under 35 U.S.C. § 134 from the Examiner's decision rejecting claims 1-5 and 8-14[1]. We have jurisdiction over this appeal under 35 U.S.C. § 6 (2002).

THE INVENTION

Appellants' invention relates to a catheter 20 having a cutting balloon 22 including an inflatable balloon 30, a plurality of incising elements 44 encapsulated in respective mounting pads 46, and a compressible sheath 50 for each incising element 44. Spec. 5, ll. 2-3, 25-26, and 30-31; Spec. 6, ll. 7-9; and figs. 1-3. During transit to the treatment site, sheath members 52a, 52b of sheath 50 protect cutting edge 48 of incising element 44. When reaching the treatment site, the inflatable balloon 30 expands so that sheath members 52a, 52b contact tissue 58. Further expansion of the balloon 30 results in radial compression of sheath components 52a, 52b so that cutting edge 48 is exposed for tissue incision. Spec. 7, ll. 3-13 and fig. 4.

Claim 1 is representative of the claimed invention and reads as follows:

> 1. A cutting balloon for use on a medical catheter to incise tissue at a treatment site in a body vessel of a patient, said cutting balloon comprising:

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[1] Claims 15-24 are indicated as allowable by the Examiner. Claims 6 and 7 are objected to by the Examiner as being dependent upon a rejected base claim and otherwise indicated as being allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claim. Final Rejection 7, mailed Oct. 2, 2007. Claims 6, 7, and 15-24 are not part of the instant appeal.

an elongated balloon defining a longitudinal axis, said balloon being inflatable from a first deflated configuration to a second radially expanded configuration;

an elongated incising element mounted on said balloon and oriented longitudinally, said incising element having a length and extending radially from said balloon to an operative surface feature capable of incising tissue; and

a radially compressible sheath mounted on said balloon along the length of said incising element and extending radially from said balloon and beyond said surface feature when said balloon is in the first configuration to protect said surface feature during transit to the treatment site, said sheath being positioned for radial compression between said tissue and said balloon to expose said surface feature for tissue incision when said balloon is inflated into the second configuration.

THE REJECTIONS

The Examiner relies upon the following as evidence of unpatentability:

Vigil	US 5,320,634	Jun. 14, 1994
Barath	US 5,616,149	Apr. 1, 1997

The following rejections are before us for review:[2]

The Examiner rejected claims 1, 2, 5, 8, and 10 under 35 U.S.C. § 102(b) as anticipated Barath.

The Examiner rejected claims 11-14 under 35 U.S.C. § 103(a) as unpatentable over Barath.

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[2] We note that the Examiner has presented new grounds of rejection and Appellants have properly responded thereto. Ans. 3 and Reply Br. 1.

The Examiner rejected claims 3, 4, and 9 under 35 U.S.C. § 103(a) as unpatentable over Barath and Vigil.

THE ISSUE

Appellants argue that Barath fails to teach a sheath that is "***radially compressed to expose the surface feature*** for tissue incision," as required by independent claim 1. App. Br. 10. Further, Appellants note that in contrast to the claimed invention, "the cutting edges 6 [of Barath] are ***exposed by the inflation of the balloon*** 2" and not by radial compression of the sheath 17 against the vessel wall. App. Br. 10 and 12.

In response, the Examiner takes the position that:

> In Figures 12-13 of Barath, the sheath 17 is shown being positioned for radial compression between the tissue 7 and the balloon 2 while also exposing the surface feature 6. Radial compression of the sheath 17 may be achieved during inflation of the balloon, wherein the sheath may be pressed and held between the tissue and the balloon, while also exposing the surface features 6, and therefore the device of Barath reads on this limitation.

Ans. 7.

The Examiner appears to take the position that because the sheath 17 of Barath is positioned between the wall 8 and the inflatable balloon 2, the sheath 17 constitutes a "radially compressible sheath." The Examiner further posits that claim 1 does not require that the exposure of the surface feature for tissue incision be caused by the radial compression of the sheath. According to the Examiner, claim 1 merely requires that the sheath 17 of Barath be positioned for radial compression, that is, be positioned so as to be

compressed between the balloon and the tissue while also exposing the surface feature for tissue incision.

Accordingly, the issue before us for consideration in the instant appeal is whether Appellants have shown that the Examiner erred in determining that the sheath 17 of Barath constitutes a "radially compressible sheath," as called for by claim 1.

SUMMARY OF DECISION

We REVERSE.

PRINCIPLES OF LAW

Claim Construction

When construing claim terminology in the United States Patent and Trademark Office, claims are to be given their broadest reasonable interpretation consistent with the specification, reading claim language in light of the specification as it would be interpreted by one of ordinary skill in the art. *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004).

Anticipation

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros, Inc.. v. Union Oil Co. of Cal.,* 814 F.2d 628, 631 (Fed. Cir. 1987).

Inherency

Under principles of inherency, when a reference is silent about an asserted inherent characteristic, it must be clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that

it would be so recognized by persons of ordinary skill. *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991).

OPINION

We begin our analysis by construing the limitation of "a radially compressible sheath... being positioned for radial compression between said tissue and said balloon to expose said surface feature for tissue incision when said balloon is inflated." As noted above, claims are to be given their broadest reasonable interpretation consistent with the specification. In this case, claim 1 requires: (1) a radially compressible sheath (2) positioned for radial compression between said tissue and said balloon and (3) a surface feature for tissue incision exposed when the balloon is inflated.

It is our finding that Barath teaches a cutting balloon catheter including a protective sheath 17 that is positioned between an inflatable balloon 2 and a vessel wall 7, 8 (tissue), so that as the balloon 2 is inflated cutting edges 6 (surface feature for tissue incision) are exposed to penetrate the vessel wall 8 (tissue). Barath, col. 5, ll. 30-34 and fig. 13. Hence, in a first instance, Barath teaches a sheath 17 that is positioned for radial compression between the tissue and the balloon, and a surface feature for tissue incision (cutting edges 6) that is exposed when the balloon is inflated. However, as shown above, claim 1 also requires a "radially compressible sheath." Although we agree with the Examiner that claim 1 does not require actual radial compression of the sheath (Ans. 7), nonetheless, in order to satisfy the limitation of claim 1, we find that the sheath 17 of Barath should be capable of radial compression. However, Barath teaches only that the protective sheath 17 is positioned between the inflatable balloon 2 and the

vessel wall 8 (tissue). We could not find any portion, and the Examiner has not pointed to any portion of Barath, that teaches sheath 17 to be capable of radial compression. Moreover, the Examiner states that:

> Radial compression of the sheath 17 *may* be achieved during inflation of the balloon, wherein the sheath *may* be pressed and held between the tissue and the balloon...

Ans. 7 (emphasis added).

Since Barath does not expressly teach that sheath 17 is capable of radial compression, the Examiner appears to rely on a theory of inherency to show that Barath anticipates the subject mater of claim 1. "Inherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art." *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002) (quoting *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999)). In this case, the question raised is whether the sheath 17 of Barath is *necessarily* capable of radial compression. Figure 13 of Barath specifically shows cutting edges 6 penetrating the vessel wall 8 prior to the radial compression of sheath 17 between balloon 2 and wall 8 (see the space between the sheath 17 and wall 8).[3] In other words, the length of the cutting edges 6 (surface feature for tissue incision) is such that penetration of the vessel wall due to expansion of the inflatable balloon occurs before the sheath 17 is radially compressed between the balloon and the vessel wall. As such, we agree with Appellants

[3] In Figure 13 of Barath the reference number "15" appears in error. The reference number 15 represents a casing shown in a different embodiment presented in Figures 9 and 10. *See also* Barath, col. 5, ll. 1-13. We find that the reference number "15" in Figure 13 represents the sheath 17.

that the sheath 17 of Barath is not *necessarily* capable of radial compression, as the Examiner suggests. *See* Reply Br. 5. In conclusion, we find that the Examiner has not provided sufficient evidence to support the finding that sheath 17 of Barath constitutes a "radially compressible sheath," as called for by claim 1.

Inasmuch as we found that Barath does not teach a cutting balloon having a "radially compressible sheath," as called for by independent claim 1, Barath does not teach all the elements of independent claim 1. Accordingly, the rejection of claims 1, 2, 5, 8, and 10 under 35 U.S.C. § 102(b) as anticipated by Barath cannot be sustained.

With respect to claims 11-14, the Examiner's proposed modification of the disclosure of Barath (Ans. 5) does not cure the deficiencies of Barath as discussed above. Accordingly, the rejection of claims 11-14 under 35 U.S.C. § 103(a) as unpatentable over Barath likewise cannot be sustained.

Finally, regarding claims 3, 4, and 9, we find that the application of Vigil does not cure the deficiency of Barath as discussed above. Accordingly, the rejection of claims 3, 4, and 9 under 35 U.S.C. § 103(a) as unpatentable over Barath and Vigil is also reversed.

CONCLUSION

Appellants have shown that the Examiner erred in determining that the sheath 17 of Barath constitutes a "radially compressible sheath," as called for by claim 1.

DECISION

The Examiner's decision to reject claims 1-5 and 8-14 is reversed.

REVERSED

mls

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